

OCT - 1 2003

K022505

NOUVAG AG
Contra-Angle Attachments Dental

510(k) Notification
July 23, 2002

SECTION 10

510(k) Summary

Submitter:

NOUVAG AG
St. Gallerstrasse 23-25
CH-9403 Goldach
Switzerland

Contact Person:

Benno Frei
Technical Director, New Product Development
Phone 0041 71 845 35 35
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Date Summary Prepared:

July 23, 2002

Device Name:

Trade Name

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Common Name

Contra-Angle Attachments Dental

Classification Name

Handpiece, Contra- and Right-Angle Attachments Dental
(per 21 CFR section 872.4200)

Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:

W & H Dentalwerk Buermoos GmbH

Device:

Surgical Contra-Angel Handpiece Attachments

510(k) :

K011061

Date Cleared:

June 21, 2001

Company: W & H Dentalwerk Buermoos GmbH
Device: Surgical Contra-Angel Handpiece Attachments
510(k) : K984508
Date Cleared: June 25, 1999

Company: NSK, INC
Device: E-Type Contra-Angle
510(k) : K962540
Date Cleared: September 12, 1996

Company: NSK, INC
Device: E-Type Speed Increaser Contra-Angle
510(k) : K972569
Date Cleared: October 08, 1997

Device Description:

All mentioned NOUVAG Contra-Angle Attachments Dental are attachments for surgical drive units. They are designed to transmit rotational movement of the motor axle of such drive units to the shank of a bur which will be inserted into the output end of the handpiece.

For this application, all these Contra-Angle Attachments contain a coupling part fittable to all surgical motors with a coupling according to ISO 3964.

The output end of the Contra-Angle Attachments contains chuck systems for accommodation of standardized bur shanks. All mentioned NOUVAG Contra-Angle Attachments Dental are designed for burs according to ISO 1797 shank-type 1.

Intended use of the Devices:

Indications are very widespread in the field of Dentistry.

Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The NOUVAG Contra-Angle Attachments Dental are substantially equivalent to other legally marketed devices in the United States. The NOUVAG Contra-Angle Attachments Dental functions in a manner similar and are intended for the same use as the Surgical Contra-Angel Handpiece Attachments designed by W & H Dentalwerk Buermoos GmbH and NSK NAKANISHI INC.

TABLE 1
TECHNOLOGICAL COMPARISON

Characteristics	NOUVAG Contra-Angle Attachments Dental	Predicate Device W & H Surgical Contra-Angel Handpieces Types	Predicate Device NSK E-Type Contra-Angle
Indications for use	Indications are very widespread in the field of implantology and surgery	Indications are very widespread in the field of implantology and surgery	Indications are very widespread in the field of implantology and surgery
Target population	No restriction	No restriction	No restriction
Design	Contra-angle	Contra-angle	Contra-angle
Materials	Alloy coated with pure chromium	Stainless steel	Stainless steel
Performance	ISO 7785-2 ISO 3964	ISO 7785-2 ISO 3964	ISO 7785-2 ISO 3964
Sterility	Sterility by user / 134°C	Sterility by user / 134°C	Sterility by user / 134°C
Biocompatibility	Acc. ISO 10993-1 / -5 / -12	Biocompatible material	Biocompatible material
Mechanical safety	ISO 7785-2	ISO 7785-2	ISO 7785-2
Human factors	Gear ratio marked on the device	Gear ratio marked on the device Color codeing	Gear ratio marked on the device Color codeing
Compatibility with other devices	Coupling dimensions acc. ISO 3964 For burs with shanks acc to ISO 1797 (2.35 mm and 1.6 mm) Push button system and Latch type	Coupling dimensions acc. ISO 3964 For burs with shanks acc to ISO 1797 (2.35 mm and 1.6 mm) Push button system	Coupling dimensions acc. ISO 3964 For burs with shanks acc to ISO 1797 (2.35 mm and 1.6 mm) Latch Type
Where used	Dental	Dental	Dental

Brief summary of nonclinical tests and results:

The NOUVAG Contra-Angle Attachments Dental have been designed and tested to applicable safety standards. The NOUVAG Contra-Angle Attachments Dental do not raise any new issues of safety, effectiveness, or performance of the product.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2003

NOUVAG AG
C/O Mr. Erich Forster
INTRATest Systems GmbH
Reusswehrstrasse 1
CH-5412 Gebenstorf,
SWITZERLAND

Re: K022505
Trade/Device Name: Contra-Angle Attachments Dental
Regulation Number: 872.4200
Regulation Name: Accessory to Dental Handpiece
Regulatory Class: I
Product Code: EGS
Dated: June 30, 2003
Received: July 3, 2003

Dear Mr. Forster:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner".

Susan Runner, DDS, MA
Interim Director

Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022505

NOUVAG AG
Contra-Angle Attachments Dental

510(k) Notification
November 29, 2002

510(k) Number (if known): K022505

Device Name: Contra- Angle Attachments Dental

Types:

1059, 5050, 5051, 5055, 5056, 5057, 5059, 5060, 5061, 5062, 5063,
5064, 5065, 5066, 5067, 5068, 5069, 5070, 5071, 5075, 5076, 5081

Indications for Use:

Indications are widespread in the field of Surgery, Implantology and Endodontic treatment.

- Surgery: 1059, 5050, 5051, 5055, 5056, 5060, 5062, 5063, 5065, 5068, 5070, 5075
- Endodontic treatment: 5057, 5059, 5061, 5064, 5066, 5067, 5069, 5071, 5076
- Speed Increaser Contra-Angle: 5081
The device is intended for use where high speed such as 200'000 rpm is required in general dentistry with or without use of coolant; such as cutting a tooth for cavity and/or crown preparation and finishing, cuttin and/or finishing of dentures, denture bases, crowns, inlays and metal plates

All devices are driven by an electric micromotor handpiece that has the ISO-3964 Coupling.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number:

K022505

(Optional Format 3-10-98)